

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA
ex rel. **THOMAS M. ZIZIC, M.D.**

V.

**Q²ADMINISTRATORS, LLC and
RIVERTRUST SOLUTIONS, INC.**

CIVIL ACTION

No. 09-5788

Norma L. Shapiro, J.

March 26, 2012

MEMORANDUM

Plaintiff, Thomas M. Zizic, M.D. (“Zizic”), brought this *qui tam* action under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (“FCA”). The government has declined to intervene, but Zizic has continued the action as relator. This action arises from contracts between the government and defendants Q²Administrators, LLC (“Q2A”) and RiverTrust Solutions, Inc. (“RTS”) for appellate review of Medicare claim denials relating to the BIO-1000, a device designed to treat osteoarthritis of the knee. *See* Compl. ¶¶ 3, 50. Zizic, a physician and President and CEO of BioniCare Medical Technologies, Inc. (“BioniCare”), a company formed to commercialize the BIO-1000, claims defendants could not have provided the statutorily required level of review by a physician or other healthcare professional because of the overwhelming volume of appeals and the small number of healthcare professionals defendants employed. Zizic states he has first-hand knowledge of the falsity of defendants’ claims because of his expertise and personal review of thousands of reconsideration denials of Medicare claims relating to the BIO-1000. *See* Compl. ¶ 93; Resp. Mot. Dismiss at 6, 33.

Zizic alleges: (1) RTS knowingly presented or caused to be presented false or fraudulent claims to the government for payment or approval and continues to do so, in violation of 31

U.S.C. § 3729(a)(1)(A) (as amended, May 2009); (2) RTS knowingly made, used, or caused to be made or used, false records or statements material to a false or fraudulent claim on the government and continues to do so, in violation of § 3729(a)(1)(B) (as amended, May 2009); and (3) defendants knowingly presented false or fraudulent claims for payments or approval to the government, in violation of §§ 3729(a)(1) and (2) (as amended, 1986). *See* Compl. at 21–31. Zizic attached to his complaint the affidavit of Wayne van Halem, a former Q2A employee, who stated “Q2A developed an internal policy to deny all claims for the BIO-1000.” *See* Compl. ex. A ¶ 13.

Defendants move to dismiss the Zizic complaint under Federal Rules of Civil Procedure 12(b)(1) (lack of subject matter jurisdiction), 12(b)(6) (failure to state a claim upon which relief can be granted), and 9(b) (failure to allege fraud with particularity). Defendants argue, *inter alia*, the court lacks jurisdiction because Zizic bases his allegations on public disclosures and is not an “original source” as defined by the FCA.

The court will grant the Q2A Motion to Dismiss (paper no. 33) and RTS Motion to Dismiss (paper no. 35). The court will deny their Motion to Strike or for Leave to Supplement Brief (paper no. 61) as moot.

I. Background

Part B of the Medicare Act (the “Act”), 42 U.S.C. § 1395j *et seq.*, reimburses providers of covered medical and health services. *See* 42 U.S.C. § 1395k(a). Covered services include certain physicians’ services, outpatient diagnostic services, and the provision of some types of durable medical equipment (“DME”), *e.g.*, oxygen tents, hospital beds, and wheelchairs for home use. 42 U.S.C. §§ 1395x(n), (s). Medicare does not reimburse providers of DME that is “[e]xperimental or investigational[.]” 42 C.F.R. § 411.15(o), or “not reasonable and necessary

for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,” 42 U.S.C. § 1395y(a)(1)(A).

A DME provider seeking Medicare reimbursement must submit a claim to a DME Medicare Administrative Contractor (“DMAC”). The DMAC determines whether provision of the DME item is reimbursable under the Act. 42 C.F.R. §§ 405.803; 414.210(a); 421.404(c)(2). A DME provider dissatisfied with a DMAC determination may request a “redetermination” by the same DMAC. 42 C.F.R. § 405.940. After an unfavorable redetermination, the DME provider may appeal to a Qualified Independent Contractor (“QIC”) for a “reconsideration.”

A reconsideration consists of an independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim. In conducting a reconsideration, the QIC reviews the evidence and findings upon which the initial determination, including the redetermination, was based, and any additional evidence the parties submit or that the QIC obtains on its own. *If the initial determination involves a finding on whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury* (under section 1862(a)(1)(A) of the Act), *a QIC’s reconsideration must involve consideration by a panel of physicians or other appropriate health care professionals*, and be based on clinical experience, the patient’s medical records, and medical, technical, and scientific evidence of record to the extent applicable.

42 C.F.R. § 405.968 (emphasis added). “Where a claim pertains to . . . the provision of items or services by a physician, a reviewing professional [of the QIC panel] must be a physician.” 42 C.F.R. § 405.968(c)(3). The QIC decision may be appealed to an Administrative Law Judge (“ALJ”), 42 C.F.R. § 405.1000, and the ALJ decision may be appealed to the Medicare Appeals Council (“MAC”), a division of the Department of Health and Human Services (“HHS”), 42 C.F.R. § 405.1100. The MAC decides coverage issues based solely on the administrative record, 42 C.F.R. § 405.1122, and its decision is subject to judicial review, 42 U.S.C. § 1395ff(b)(1)(A);

42 C.F.R. § 405.1136. *See, e.g., Almy v. Sebelius*, 749 F. Supp. 2d 315 (D. Md. 2010) (judicial review of MAC decisions relating to the BIO-1000).

Defendants are QICs contracted by the Centers for Medicare & Medicaid Services to conduct reconsiderations. Q2A conducted reconsiderations for all DMAC redeterminations from July 2005 to December 31, 2006. RTS conducted all reconsiderations thereafter. *See* Compl. ¶¶ 12, 15.

II. Discussion

A. False Claims Act

The False Claims Act (“FCA”) prohibits persons from knowingly submitting false claims to the government. A private person with knowledge of false claims (a “relator”) who brings a *qui tam* action on behalf of the government is awarded a percentage of any resulting recovery. *See* 31 U.S.C. §§ 3730(a), (d); *see also United States ex rel. Dunleavy v. Cnty. of Del.*, 123 F.3d 734, 738 (3d Cir. 1997). “The primary purpose of the FCA ‘is to indemnify the government—through its restitutionary penalty provisions—against losses caused by a defendant’s fraud.’” *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 304 (3d Cir. 2011) (citation omitted).

Prior to May 2009, § 3729(a) of the FCA imposed liability on:

Any person who—

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval; [or]

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government[.]

In May 2009, Congress enacted the Fraud Enforcement and Recovery Act (“FERA”), which amended § 3729(a) to impose liability on:

[A]ny person who—

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]

As amended § 3729(a) eliminates the intent requirement where a party submits claims to a third party rather than directly to the government. *See United States ex rel. Loughren v. Unum Group*, 613 F.3d 300, 307 n.7 (1st Cir. 2010). Here it is undisputed defendants contracted directly with the government for appellate review of Medicare claim denials. The issue here is the same under either version of § 3729(a).

B. Rule 12(b)(1): lack of subject matter jurisdiction

A complaint must be dismissed if the court lacks subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). The plaintiff bears the burden of establishing subject matter jurisdiction. *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991).

Prior to March 2010, § 3730(e)(4)(A) of the FCA provided:

No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

This section precluded *qui tam* actions “based on information that would have been equally available to strangers to the fraud transaction had they chosen to look for it as it was to the relator.” *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1155–56 (3d Cir. 1991). Congress amended § 3730(e)(4) in March 2010; § 3730(e)(4)(A) now provides:

The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
(ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
(iii) from the news media,
unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

Zizic filed the complaint in December 2009, three months before Congress amended § 3730(e)(4). The Supreme Court has held the amended § 3730(e)(4) does not apply retroactively to actions pending at the time of amendment. *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1, 176 L. Ed. 2d 225 (2010). Because the Zizic action was pending at the time of amendment, the court will apply pre-amendment § 3730(e)(4).

A challenge to subject matter jurisdiction under Rule 12(b)(1) may be “facial” or “factual.” *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). A facial challenge concerns a deficiency with the pleading, and a factual challenge concerns “the actual failure of relator’s claims to comport with the jurisdictional prerequisites contained in 31 U.S.C. § 3730(e)(4).” *United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir. 2007). While a court reviewing a facial challenge may consider only the complaint and its attachments, a court reviewing a factual challenge may consider external evidence. *Gould*, 220 F.3d at 176. Defendants argue Zizic’s allegations were publicly disclosed in administrative hearings and prior litigation, and Zizic was not an original source because he had no inside information. Because these arguments address the failure of Zizic’s claims to satisfy the jurisdictional prerequisites of § 3730(e)(4), defendants have factually challenged the court’s jurisdiction. The court may consider external evidence in determining jurisdiction.

1. Public disclosure

The court must first determine “whether the information was disclosed via one of the sources listed in § 3730(e)(4)(A)[.]” *Atkinson*, 473 F.3d at 519. Section 3730(e)(4)(A) includes federal administrative and civil hearings as sources of public disclosure.¹ Both federal administrative hearings and civil litigation hearings are § 3730(e)(4)(A) public disclosures.

The court must then determine “whether the relator’s complaint is based on those disclosures”; *i.e.*, whether it is “‘supported by’ or ‘substantially similar to’ the disclosed allegations and transactions.” *Atkinson*, 473 F.3d at 519 (citation omitted). A disclosure supports an allegation of fraud if it expressly alleges fraud or reveals both a misrepresented state of facts and a true state of facts to warrant an inference of fraud. *See United States ex rel. Dunleavy v. Cnty. of Del.*, 123 F.3d 734, 741 (3d Cir. 1997) (quoting *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994)).

In *Dunleavy*, the relator sued Delaware County, Pennsylvania, on behalf of the United States and sought damages and costs for the County’s alleged violations of the FCA. The County used funds provided by the Department of Housing and Urban Development (“HUD”) to acquire land. The agreement between the County and HUD limited the County’s use of the funds and imposed reporting requirements on the County. *Id.* at 737. The County later sold the land to the Pennsylvania Department of Transportation for the planned construction of a highway but allegedly failed to repay money received for the land to HUD. *Id.* The district court dismissed

¹ The amended § 3730(e)(4)(A) changed “criminal, civil, or administrative hearing” to “Federal criminal, civil, or administrative hearing in which the Government or its agent is a party.” *Cf. Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1411, 176 L. Ed. 2d 225 (2010) (holding “administrative” in pre-amendment § 3730(e)(4)(A) is not limited to federal sources). Here the administrative and civil hearings are federal; the issue is the same under either version of § 3730(e)(4)(A).

the complaint under Rule 12(b)(1) because the relator based his action solely on public disclosures including a grantee performance report allegedly omitting the County's receipt of money for the land. *Id.* at 735–36. The Court of Appeals found no disclosure expressly alleged fraud. *Id.* at 741. The grantee performance report was “the only source that, if publicly disclosed, would complete the inference of fraud.” *Id.* at 743. Other documents revealed the true state of facts (*i.e.*, the County's retention of proceeds from the sale of the land) but only the grantee performance report revealed the misrepresented state of facts (*i.e.*, the County's failure to report the proceeds to HUD). *Id.* “Without the benefit of [the relator's] insider position, someone investigating government fraud would be able to ascertain that the County had not fulfilled its reporting obligation only if that individual had access to the [grantee performance report].” *Id.* at 744. Although the grantee performance report warranted an inference of fraud, the Court reversed the district court dismissal of the complaint under § 3730(e)(4)(A) and remanded for further proceedings because the grantee performance report was not publicly disclosed. *Id.* at 746.

Prior BIO-1000 administrative hearings revealed defendants contracted with the government to conduct reconsiderations performed by appropriate healthcare professionals (the misrepresented state of facts), and conducted those reconsiderations inconsistently (the true state of facts). The inconsistent reviews suggested to Zizic defendants did not provide reconsiderations as claimed. The hearing revelations warranted an inference of fraud.

Prior litigation also warranted an inference of fraud. In *Almy v. Sebelius*, 749 F. Supp. 2d 315 (D. Md. 2010), the Chapter 7 Trustee for the BioniCare bankruptcy estate sought review of eight MAC decisions relating to Medicare claim denials for the BIO-1000. The court, finding the MAC decisions were supported by substantial evidence and not arbitrary and capricious,

affirmed and granted defendant's cross-motion for summary judgment. In plaintiff's summary judgment motion, she alleged:

Although the Medicare regulations required physician review at the QIC for claims for services or items provided by a physician, only two of the claims in the 535 Decision show any indicia of physician review and only a small number of claims in the 535 Decision have indicia of nurse review. None of the claims in the other cases have any evidence of nurse or physician review. In fact, the QIC that originally reviewed claims for the BIO-1000 subjected none of the claims to physician or nurse review.

Pl.'s Mot. Summ. J. at ex. 3 ¶ 66, *Almy*, 749 F. Supp. 2d 315 (No. RDB-08-1245) (paper no. 41-9). Zizic's claim is substantially similar to this allegation. *See Atkinson*, 473 F.3d at 519. The *Almy* plaintiff moved for summary judgment on November 6, 2009; Zizic filed his *qui tam* complaint on December 4, 2009. Zizic bases his claim on § 3730(e)(4)(A) public disclosures.

2. Original source

Even though Zizic bases his claim on § 3730(e)(4)(A) public disclosures, his claim can withstand the motions to dismiss for lack of jurisdiction if he is an original source. *See* 31 U.S.C. § 3730(e)(4)(A).

An original source is an individual "who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information."

§ 3730(e)(4)(B).² The Court of Appeals defines “direct knowledge” as “knowledge obtained without any ‘intervening agency, instrumentality, or influence: immediate.’” *United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 520 (3d Cir. 2007) (citation omitted). The Court of Appeals defines “independent knowledge” as “knowledge that does not depend on public disclosures.” *Id.* If a relator bases knowledge solely on § 3730(e)(4)(A) public disclosures, the relator does not have “direct and independent knowledge” under § 3730(e)(4)(B). *Id.* at 521.

In *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149 (3d Cir. 1991), the Court of Appeals affirmed a district court dismissal of an FCA *qui tam* action based on memoranda disclosed in prior litigation. The relator argued the action was not based on the memoranda because knowledge of the insurance industry allowed the relator to understand the complex fraudulent scheme of the defendant. The Court held “the relator must possess substantive information about the particular fraud, rather than merely background information which enables a putative relator to understand the significance of a publicly disclosed transaction or allegation.” *Stinson*, 944 F.2d at 1160 (citation omitted). Because the relator obtained knowledge through two intermediaries (*i.e.*, the author of the memoranda and the discovery process in prior litigation), it did not have direct knowledge.

² In March 2010, Congress amended § 3730(e)(4)(B) to define “original source” as: an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

Because the Zizic action was pending at the time of amendment, the court will apply pre-amendment § 3730(e)(4)(B). *See supra* II.B.

Because the relator had only background information, it did not have independent knowledge. The relator was not an original source. *See id.* at 1160–61.

Zizic lacks direct knowledge to the extent his claims depend on the affidavit of Wayne van Halem (“van Halem”). The complaint cites van Halem as merely “substantiat[ing]” the information of which Zizic already had “first-hand knowledge[,]” *see* Compl. at 17, but van Halem adds facts that were not revealed through Zizic’s review of reconsiderations. For example, van Halem states “Q2A developed an internal policy to deny all claims for the BIO-1000.” *See id.* ¶ 104; ex. A ¶ 13. Because Zizic obtained information of the Q2A internal policy through van Halem, Zizic lacks direct knowledge of the Q2A internal policy. *See Stinson*, 944 F.2d at 1160–61.

To the extent Zizic’s claims do not depend on the van Halem affidavit, he lacks independent knowledge because his knowledge is based on § 3730(e)(4)(A) public disclosures. *See Atkinson*, 473 F.3d at 521. Like the relator in *Stinson*, Zizic lacks substantive information of the fraud he alleges. Instead, Zizic has “merely background information” that “enables [him] to understand the significance of . . . publicly disclosed transaction[s] or allegation[s].” *See Stinson*, 944 F.2d at 1160. Because Zizic lacks independent knowledge, he is not an original source under § 3730(e)(4)(B). The court does not have jurisdiction over his action. *See* § 3730(e)(4)(A). The motions to dismiss under Rule 12(b)(1) will be granted.

C. Motion to strike

The parties dispute whether Zizic voluntarily provided information to the government before filing his action. *See* § 3730(e)(4)(B). After oral argument on the summary judgment motions, Zizic wrote a letter to the court and stated he provided information to the government

before filing his action.³ Defendants move to strike the letter, or, in the alternative, for leave to file a supplemental brief in response. *See* Def. Mot. Strike (paper no. 61). Because we have no jurisdiction over this action, it does not matter whether relator voluntarily provided information to the government. The court will deny the motion to strike as moot.

III. Conclusion

For the foregoing reasons, the court will grant the Q2A Motion to Dismiss (paper no. 33) and the RTS Motion to Dismiss (paper no. 35). The court will deny the Motion to Strike or for Leave to Supplement Brief (paper no. 61) as moot. Because we have no jurisdiction over this action, we need not consider whether Zizic has alleged fraud with the particularity required by Federal Rule of Civil Procedure 9(b). An appropriate order follows.

³ Zizic stated he first provided information to the government on November 24, 2009. This is more than two weeks after the *Almy* plaintiff moved for summary judgment. *See supra* II.B.1.